11-8-04

AF/1617 $
IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of: T. Kosoglou et al.	Examiner: San-Ming R. Hui
Serial No.: 10/056,680	Group Art Unit: 1617
Filed: January 25, 2002	Atty. Docket No.: CV01492K
For: Combinations of Sterol Absorption Inhibitor(s) with Blood Modifiers for Treating Vascular Indications	

MAIL STOP APPEAL BRIEF – PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ON APPEAL FROM THE PRIMARY EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANT'S BRIEF UNDER 37 C.F.R. § 1.192

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as Express Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

11/05/2004 Chris Reichert
Date Signature

Chris Reichert
Typed Name of Person Signing Certificate

TABLE OF CONTENTS

I

REAL PARTY IN INTEREST

The real party in interest in this Appeal is assignee Schering Corporation, having a principal place of business 2000 Galloping Hill Road, Kenilworth, NJ 07033.

II

RELATED APPEALS AND INTERFERENCES

As the legal representative of Appellant, the undersigned attorney has no knowledge of any appeals or interferences directly related to this Appeal.

III

STATUS OF THE CLAIMS

This is an original patent application in which claims 1 and 3-48 are pending and claims 4-10, 12-17, 21-34, 38-41, 46 and 48 have been withdrawn from consideration by the Examiner. Claim 2 was canceled in the Amendment of May 10, 2004 ("Amendment").

Claims 1-3, 11, 18-20, 35-37, 42-45 and 47 (pending) were finally rejected under 35 U.S.C. § 103(a) in an Office Action mailed July 28, 2004 ("Final Office Action"). Fourteen (14) pending claims (1, 3, 11, 18-20, 35-37, 42-45 and 47) are at issue in this Appeal.

IV

STATUS OF AMENDMENTS

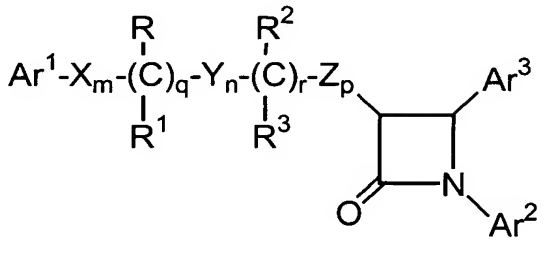
No claims were amended after final rejection. A copy of the claims involved in this Appeal is contained in the Appendix attached hereto.

V

SUMMARY OF THE INVENTION

Applicants have discovered compositions and combinations comprising:

(a) at least one sterol absorption inhibitor represented by Formula (I):



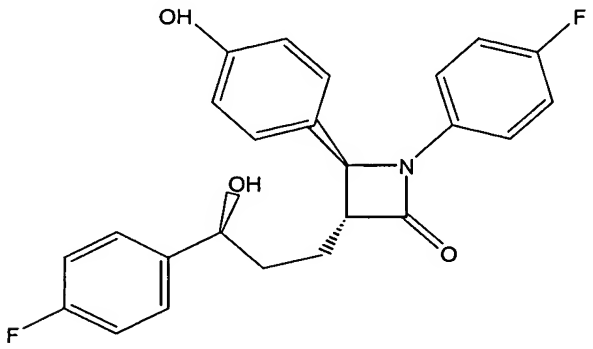
(I)

isomers, prodrugs, or pharmaceutically acceptable salts or solvates thereof (see original claim 2 for moiety definitions); and

(b) at least one blood modifier for vascular conditions which is different from component (a) above

(original claim 2 and page 15, line 23 - page 17, line 4 of the specification).

In the Office Action of August 27, 2003, Applicants were required to elect a species of sterol absorption inhibitor, blood modifier, and third therapeutic agent. Applicants provisionally elected ezetimibe, which is represented by Formula (II) below:



(II).

Ezetimibe is the active ingredient in ZETIA® pharmaceutical formulation, which is commercially available from MSP (Merck Schering-Plough) Pharmaceuticals, Inc. See Response to Restriction Requirement and Election of Species of September 9, 2003 ("Response").

In the same Response, Applicants provisionally elected aspirin as the blood modifier and simvastatin (an HMG CoA reductase inhibitor) as the third therapeutic agent.

The claimed compositions, combinations and treatment methods can be useful for treating vascular conditions and/or lowering concentration of a sterol in plasma in a mammal (page 72, lines 13-18 of the specification).

VI

ISSUE

Has a Prima Facie Case of Obviousness Under 35 U.S.C. § 103 Over EP 0720599 ("Rosenblum et al.") and WO 99/47123 ("Ullah") in view of Frei (Proc Soc Exp Biol Med. 1999 Dec; 222(3): 196-204) been Established?

VII

GROUPING OF CLAIMS

All fourteen (14) of pending claims 1, 3, 11, 18-20, 35-37, 42-45 and 47 in the present application have been treated together. Claims 35-37 (Group II) do not stand and fall together with claims 1, 3, 11, 18-20 and 47 (Group I) because they recite an additional component, namely an HMG CoA reductase inhibitor. Claims 42-45 (Group III) do not stand and fall together with the claims of Group I or Group II because they recite an additional component, an antioxidant or vitamin.

VIII

ARGUMENT

I. The Rejection

Claims 1, 3, 11, 18-20, 35-37, 42-45 and 47 have been rejected under 35 U.S.C. § 103(a) over EP 0720599 ("Rosenblum et al.") and WO 99/47123 ("Ullah") in view of Frei (Proc Soc Exp Biol Med. 1999 Dec; 222(3): 196-204).

The reasons for rejection are set forth in the Final Office Action, summarized as follows:

Rosenblum et al. disclose that compositions including the compound of Formula II can be combined with HMG CoA reductase inhibitors such as

simvastatin to reduce cholesterol and risk of atherosclerosis (Final Office Action at page 3). Ullah teaches a composition comprising statins, such as simvastatin, in combination with aspirin, for cholesterol lowering and treating or reducing the risk of developing atherosclerosis (Final Office Action at page 3).

It is acknowledged that the primary references do not expressly teach the claimed composition comprising the compound of Formula II, aspirin and simvastatin together or that antioxidants be incorporated into such as composition (Final Office Action at page 3). Frei teaches that antioxidants such as vitamins C or E can be useful for inhibiting atherogenesis and normalizing vascular functions. (Final Office Action at page 4).

It is alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the compound of Rosenblum et al. into Ullah, which are known to be useful to reduce cholesterol level and the risk of atherosclerosis individually, into a single composition useful for the very same purpose, citing *In re Kerkoven*, 205 U.S.P.Q. 1069 (Final Office Action at page 4). Further, one of ordinary skill in the art would have been motivated to include an antioxidant since vitamin C, an antioxidant, is known to inhibit the development of atherosclerosis (Final Office Action at page 4).

II. The Prior Art

Rosenblum et al. disclose the compound of Formula II (Page 29, Ex. 6). Rosenblum et al. disclose starch-based pharmaceutical compositions including compounds of Formula I of Rosenblum et al. (Ex. A and B Page 29). Rosenblum et al. teach that the active compounds therein can be combined with HMG CoA reductase inhibitors, such as simvastatin (Page 5, paragraph 0028). Rosenblum et al. also disclose that the active compounds are useful for reducing cholesterol and the risk of atherosclerosis (claims).

Ullah discloses the use of aspirin for reducing myocardial infarction and a statin (such as simvastatin) for lowering cholesterol and preventing or treating atherosclerosis at page 1, lines 14-18, in combination.

Frei discloses that antioxidants may inhibit atherogenesis and improve vascular function by two different mechanisms (Abstract). Lipid-soluble antioxidants present in LDL, such as vitamin C, can inhibit LDL oxidation (Abstract). Antioxidants present in the cells of the vascular wall decrease cellular production and release of reactive oxygen species (ROS), inhibit endothelial activation and improve the biologic activity of ENDO (Abstract).

II. The Required Prima Facie Case of Obviousness Under 35 U.S.C. § 103 Has Not Been Established

When making a rejection under 35 U.S.C. § 103, the Examiner has the burden of establishing a prima facie case of obviousness. In re Fritch, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The Examiner can satisfy this burden only by showing an objective teaching in the prior art, or knowledge generally available to one of ordinary skill in the art, which would lead an individual to combine the relevant teachings of the references [and/or the knowledge] in the manner suggested by the Examiner. Id.; In re Fine, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

The mere fact that the prior art could be modified does not make the modification obvious *unless the prior art suggests the desirability of the modification* (emphasis added). In re Fritch, 23 U.S.P.Q.2d at 1784; In re Laskowski, 10 U.S.P.Q.2d 1397, 1398 (Fed. Cir. 1989); In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984).

"The ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence." Manual of Patent Examining Procedure, (Rev. 1, Feb. 2003) § 716.01(d) and In re Oetiker, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

Claims 1, 3, 11, 18-20 and 47

Claims 1 and 47 recite a composition and therapeutic combination, respectively, comprising a sterol absorption inhibitor of Formula I shown above, isomers, prodrugs, or pharmaceutically acceptable salts or solvates thereof; and at least one blood modifier for vascular conditions which is different from the sterol absorption inhibitor.

Claim 3 depends from claim 1 and recites the compound of Formula II (ezetimibe) as the compound of Formula I.

Claim 11 depends from claim 1 and recites specific groups of blood modifiers. Claims 18-20 depend directly or indirectly from claim 1 and recite that the blood modifier is a platelet inhibitor, such as aspirin.

It is respectfully submitted that the combination of the references cited as rendering the claimed invention obvious is improper because there is no suggestion in the cited references to combine the claimed components of sterol absorption inhibitor (such as that of Formula (I) (e.g., ezetimibe)) and blood modifier such as aspirin.

Applicants wish to emphasize that claim 1 does not require the presence of a third component, such as a statin.

With respect to patentability of a composition or combination of a sterol absorption inhibitor and blood modifier such as aspirin (*without the presence of a statin*), Rosenblum does not suggest or disclose combinations of a sterol absorption inhibitor and blood modifier such as aspirin. Ullah does not suggest or disclose combinations of a sterol absorption inhibitor and blood modifier such as aspirin.

In Ullah, *aspirin is disclosed as being useful for reducing myocardial infarction* at page 1, lines 14-18, *not for treating atherosclerosis*. The statin in Ullah is disclosed as lowering cholesterol and treating atherosclerosis. Id.

In the final Office Action at pages 4 and 5, *In re Kerkoven* was cited as supporting the argument that combining the compositions of Rosenblum and Ullah, which are known to be useful to reduce cholesterol level and the risk of

atherosclerosis individually, into a single composition useful for the very same purpose would be considered obvious.

However, the invention of claims 1, 3, 11, 18-20 and 47 is for a sterol absorption inhibitor and blood modifier such as aspirin and does not require a statin. Ullah does *not* disclose aspirin as being useful for lowering cholesterol or treating atherosclerosis. Therefore *In re Kerkoven* does not apply since Ullah does not disclose aspirin as having the same purpose as a cholesterol absorption inhibitor or HMG CoA reductase inhibitor, namely to lower cholesterol or treat atherosclerosis.

Frei does not disclose sterol absorption inhibitors or blood modifiers such as aspirin. Even if the teachings of Frei were combined with those of Rosenblum et al. and Ullah as suggested in the Final Office Action, one skilled in the art would not be motivated to provide a composition having a sterol absorption inhibitor and blood modifier such as aspirin.

Therefore, the prima facie case of obviousness based upon Rosenblum et al., Ullah and Frei has not been established and the rejection of claims 1, 3, 11, 18-20 and 47 should be reconsidered and withdrawn.

Claims 35-37

Claims 35-37 depend from claim 1 and further recite at least one HMG CoA reductase inhibitor, such as simvastatin. Thus the composition would comprise sterol absorption inhibitor, blood modifier such as aspirin, and HMG CoA reductase inhibitor, such as simvastatin.

It is respectfully submitted that the combination of the references cited as rendering the claimed invention obvious is improper because there is no suggestion in the cited references to combine the claimed components of sterol absorption inhibitor (such as that of Formula (I) (e.g., ezetimibe)), blood modifier such as aspirin, and HMG CoA reductase inhibitor.

Rosenblum et al. and Ullah provide no motivation for a triple combination of sterol absorption inhibitor, blood modifier such as aspirin, and HMG CoA reductase inhibitor. Frei only discloses antioxidants as useful for

treating atherosclerosis and therefore is not relevant to the rejection of these claims.

Therefore, the prima facie case of obviousness based upon Rosenblum et al., Ullah and Frei has not been established and the rejection of claims 35-37 should be reconsidered and withdrawn.

Claims 42-45

Claims 42-45 depend from claim 1 and further recite at least one antioxidant or vitamin. Thus the composition would comprise sterol absorption inhibitor, blood modifier such as aspirin, and antioxidant or vitamin.

Applicants wish to emphasize that claim 1 does not require the presence of a third component, such as a statin.

With respect to patentability of a composition or combination of a sterol absorption inhibitor, blood modifier such as aspirin and antioxidant or vitamin (*without the presence of a statin*), Rosenblum does not suggest or disclose combinations of a sterol absorption inhibitor and blood modifier such as aspirin. Ullah does not suggest or disclose combinations of a sterol absorption inhibitor and blood modifier such as aspirin.

In Ullah, *aspirin is disclosed as being useful for reducing myocardial infarction* at page 1, lines 14-18, *not for treating atherosclerosis*. The statin in Ullah is disclosed as lowering cholesterol and treating atherosclerosis. Id.

In the final Office Action at pages 4 and 5, *In re Kerkoven* was cited as supporting the argument that combining the compositions of Rosenblum and Ullah, which are known to be useful to reduce cholesterol level and the risk of atherosclerosis individually, into a single composition useful for the very same purpose would be considered obvious.

However, the invention of claims 42-45 is for a sterol absorption inhibitor, blood modifier such as aspirin and antioxidant or vitamin. Ullah does *not* disclose aspirin as being useful for lowering cholesterol or treating atherosclerosis. Therefore *In re Kerkoven* does not apply since Ullah does

not disclose aspirin as having the same purpose as a cholesterol absorption inhibitor.

Frei does not disclose sterol absorption inhibitors or blood modifiers such as aspirin. Even if the teachings of Frei were combined with those of Rosenblum et al. and Ullah as suggested in the Final Office Action, one skilled in the art would not be motivated to provide a composition having a having a sterol absorption inhibitor, blood modifier such as aspirin and vitamin or antioxidant.

Therefore, the prima facie case of obviousness based upon Rosenblum et al., Ullah and Frei has not been established and the rejection of claims 42-45 should be reconsidered and withdrawn.

Accordingly, Applicants respectfully request that the § 103(a) rejection of claims 1, 3, 11, 18-20, 35-37, 42-45 and 47 be reconsidered and withdrawn.

Respectfully submitted,

Date: November 5, 2004

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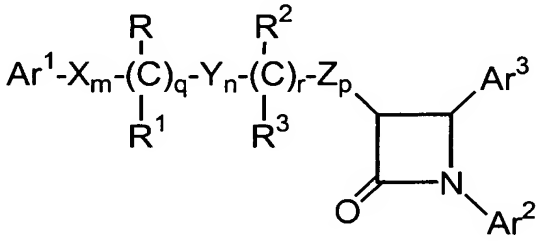
APPENDIX - Claims on Appeal

1. A composition comprising:

(a) at least one sterol absorption inhibitor or pharmaceutically acceptable salt or solvate thereof or prodrug of the at least one sterol absorption inhibitor or of the salt or solvate thereof

wherein the at least one sterol absorption inhibitor is represented by Formula (I):



(I)

or isomers thereof, or pharmaceutically acceptable salts or solvates of the compounds of Formula (I) or of the isomers thereof, or prodrugs of the compounds of Formula (I) or of the isomers, salts or solvates thereof,

wherein:

Ar^1 and Ar^2 are independently selected from the group consisting of aryl and R^4-substituted aryl;

Ar^3 is aryl or R^5-substituted aryl;

X, Y and Z are independently selected from the group consisting of $-CH_2-$, -CH(lower alkyl)- and -C(dilower alkyl)-;

R and R^2 are independently selected from the group consisting of -OR^6,

-$O(CO)R^6$, -$O(CO)OR^9$ and -$O(CO)NR^6R^7$;

R^1 and R^3 are independently selected from the group consisting of hydrogen, lower alkyl and aryl;

q is 0 or 1;

r is 0 or 1;

m, n and p are independently selected from 0, 1, 2, 3 or 4; provided that at least one of q and r is 1, and the sum of m, n, p, q and r is 1, 2, 3, 4, 5

or 6; and provided that when p is 0 and r is 1, the sum of m, q and n is 1, 2, 3, 4 or 5;

R^4 is 1-5 substituents independently selected from the group consisting of lower alkyl, $-OR^6$, $-O(CO)R^6$, $-O(CO)OR^9$, $-O(CH_2)_{1-5}OR^6$, $-O(CO)NR^6R^7$, $-NR^6R^7$, $-NR^6(CO)R^7$, $-NR^6(CO)OR^9$, $-NR^6(CO)NR^7R^8$, $-NR^6SO_2R^9$, $-COOR^6$, $-CONR^6R^7$, $-COR^6$, $-SO_2NR^6R^7$, $S(O)_{0-2}R^9$, $-O(CH_2)_{1-10}-COOR^6$, $-O(CH_2)_{1-10}CONR^6R^7$, -(lower alkylene)$COOR^6$, $-CH=CH-COOR^6$, $-CF_3$, -CN, $-NO_2$ and halogen;

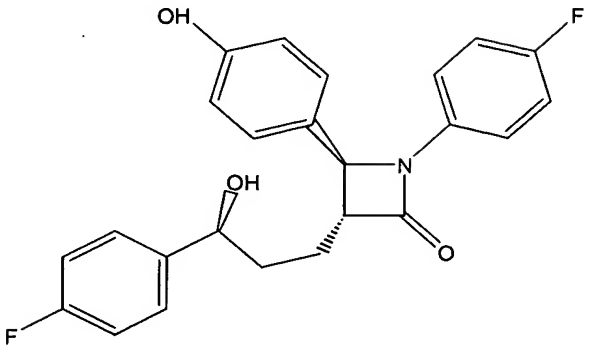
R^5 is 1-5 substituents independently selected from the group consisting of
$-OR^6$, $-O(CO)R^6$, $-O(CO)OR^9$, $-O(CH_2)_{1-5}OR^6$, $-O(CO)NR^6R^7$, $-NR^6R^7$, $-NR^6(CO)R^7$, $-NR^6(CO)OR^9$, $-NR^6(CO)NR^7R^8$, $-NR^6SO_2R^9$, $-COOR^6$, $-CONR^6R^7$,
$-COR^6$, $-SO_2NR^6R^7$, $S(O)_{0-2}R^9$, $-O(CH_2)_{1-10}-COOR^6$, $-O(CH_2)_{1-10}CONR^6R^7$,
-(lower alkylene)$COOR^6$ and $-CH=CH-COOR^6$;

R^6, R^7 and R^8 are independently selected from the group consisting of hydrogen, lower alkyl, aryl and aryl-substituted lower alkyl; and

R^9 is lower alkyl, aryl or aryl-substituted lower alkyl; and

(b) at least one blood modifier for vascular conditions which is different from component (a) above.

3. The composition according to claim 1, wherein the sterol absorption inhibitor is represented by Formula (II) below:



(II)

or pharmaceutically acceptable salts or solvates thereof, or prodrugs of the compound of Formula (II) or of the salts or solvates thereof.

11. The composition according to claim 1, wherein the at least one blood modifier is selected from the group consisting of anti-coagulants, antithrombotic agents, fibrinogen receptor antagonists, platelet inhibitors, platelet aggregation inhibitors, hemorrheologic agents, lipoprotein associated coagulation inhibitor, Factor VIIa inhibitors, Factor Xa inhibitors and combinations thereof.

18. The composition according to claim 11, wherein the at least one blood modifier is a platelet inhibitor.

19. The composition according to claim 18, wherein the platelet inhibitor is selected from the group consisting of cilostazol, clopidogrel bisulfate, epoprostenol, epoprostenol sodium, ticlopidine hydrochloride, aspirin, ibuprofen, naproxen, sulindae, idomethacin, mefenamate, droxicam, diclofenac, sulfinpyrazone, piroxicam, dipyridamole and combinations thereof.

20. The composition according to claim 19, wherein the platelet inhibitor is aspirin.

35. The composition according to claim 1, further comprising at least one cholesterol biosynthesis inhibitor.

36. The composition according to claim 35, wherein the at least one cholesterol biosynthesis inhibitor comprises at least one HMG CoA reductase inhibitor.

37. The composition according to claim 36, wherein the at least one HMG CoA reductase inhibitor is simvastatin.

42. The composition according to claim 1, further comprising at least one antioxidant or vitamin.

43. The composition according to claim 1, wherein the at least one blood modifier is administered to a mammal in an amount ranging from about 1 to about 1000 milligrams of blood modifier per day.

44. The composition according to claim 1, wherein the at least one sterol absorption inhibitor is administered to a mammal in an amount ranging from about 0.1 to about 1000 milligrams of sterol absorption inhibitor per day.

45. A pharmaceutical composition for the treatment of vascular conditions, diabetes, obesity or lowering a concentration of a sterol in plasma of a mammal, comprising a therapeutically effective amount of the composition of claim 1 and a pharmaceutically acceptable carrier.

47. A therapeutic combination comprising:

(a) a first amount of at least one sterol absorption inhibitor or pharmaceutically acceptable salt or solvate thereof or prodrug of the at least one sterol absorption inhibitor or of the salt or solvate thereof; and

(b) a second amount of at least one blood modifier different from the sterol absorption inhibitor,

wherein the first amount and the second amount together comprise a therapeutically effective amount for the treatment of vascular conditions, diabetes, obesity or lowering a concentration of a sterol in plasma of a mammal.

FEE TRANSMITTAL for FY 2005

NOV 0 5 2004

PATENT & TRADEMARK OFFICE

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($)340.00

Complete if Known	
Application Number	10/056,680
Filing Date	January 25, 2002
First Named Inventor	T. Kosoglou et al.
Examiner Name	San-Ming R. Hui
Art Unit	1617
Attorney Docket No.	CV01492K

METHOD OF PAYMENT (*check all that apply*)

☒ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☐ Deposit Account:

Deposit Account Number: 23-0650

Deposit Account Name:

The Director is authorized to: (*check all that apply*)

☐ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below	Fee Paid
Total Claims	-20** =		X		=
Independent Claims	-3** =		X		=
Multiple Dependent					=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	**Reissue independent claims over original patent
1205	18	2205	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	340	2401	165	Notice of Appeal	
1402	340	2402	165	Filing a brief in support of an appeal	340.00
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($)340.00

SUBMITTED BY

(Complete (*if applicable*))

Name (*Print/Type*)	Ann Marie Cannoni	Registration No. (*Attorney/Agent*)	35,972	Telephone	412-471-8815
Signature				Date	November 5, 2004

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